UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

JUN 1 8 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Public Interest Documentation of Pyroxsulam (XDE-742) for Post-emergence Control of Annual Grass and Broadleaf Weeds in Spring and Winter Wheat Including Durum (DP # 332134 and DP # 332135).

FROM: Sunil Ratnayake, Biologist
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THRU: Arnet Jones, Chief
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TO: Joanne Miller, Product Manager
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Registration Division (7505 P)

PRODUCT REVIEW PANEL: June 6, 2007

SUMMARY

BEAD was requested by the Registration Division to review submitted information by Dow AgroSciences LLC to support a public interest finding for pyroxsulam. Pyroxsulam (XDE-742) is a new post-emergence herbicide developed for selective control of economically important annual grass and broadleaf weeds in winter and spring wheat including durum. The registrant submitted comparative efficacy data from studies conducted in Australia and Canada, as well as countries in Europe, Asia, and Africa, but studies have not been conducted in the U.S. Currently, many herbicides registered for grass and broadleaf weed control in wheat production are available in the U.S. market. BEAD reviewed the submission and believes that pyroxsulam provides an equivalent weed control to the available registered herbicides. The data needed to make a direct comparison of efficacy, application rate, residual activity, and economic benefits of XDE-742 with many registered herbicides used for the grasses and broadleaf weed control of wheat production in the U.S. were not included in the submission. Therefore, the registrant's claims cannot be substantiated. Based on the information submitted by the registrant, and available information on the currently registered herbicides used in wheat production, BEAD believes that pyroxsulam does not satisfy the two criteria: 1) there is a need for the new herbicide that is not being met by currently registered pesticides; 2) the benefits from the new pesticide are greater than those from currently

registered pesticides or non-chemical control measures that BEAD evaluated for granting the public interest finding status for a pesticide.

Agency Public Interest Finding Policy

FIFRA section 3(C)(7)(C) authorizes the issuance of a conditional registration for a new pesticide with specific restrictions. This interim registration allows temporary use of a pesticide while full registration is being pursued. All three of the following conditions must be met for a conditional registration: 1) insufficient time has elapsed for the generation of data, since the requirement for that data was imposed; 2) use of the pesticide will not cause unreasonable adverse effects; and 3) use of the pesticide is in the public interest.

The registration of a new pesticide ingredient is presumed to be in the public interest if one or more of the following criteria are applicable: 1) it involves a replacement for another pesticide that is of continuing concern to the Agency; 2) it involves a use for which a section 18 emergency exemption has been granted, if the basis for the exemption was the lack of a suitable alternative; and 3) involves a use against a pest of public health significance.

Pesticides which do not meet any of the criteria listed above for the presumption of public interest, one of the following three criteria must be met: 1) there is a need for the new pesticide that is not being met by currently registered pesticides; 2) the new pesticide is less risky than currently registered pesticides; 3) the benefits from the new pesticide are greater than those from currently registered pesticides or non-chemical control measures. BEAD's review focuses on items 1 and 3.

Wheat Production in the U.S.

Wheat is a major cereal crop produced in the U.S. Major wheat producing states and the value of wheat production in those states in 2006 is shown in Table 1. Winter wheat represents 70-80% of the total U.S. wheat production. The winter wheat producing areas in the U.S. include the High Plains states extending south from South Dakota to Texas and the Pacific Northwest states. Winter wheat is also an important rotational crop in most Midwestern and Southeastern states. In 2006, the major winter wheat producing states are Kansas, Texas, and Oklahoma, whereas the spring wheat and durum wheat producing states are Idaho, Minnesota, Montana, North Dakota, South Dakota, and Washington (Table 2). In 2004, a total of 43.3 million acres of winter wheat was planted in the U.S. and value of the crop was $ 4.9 billion (10). Also in 2004, 13.2 million acres of spring wheat was planted in the U.S. and the value of the crop was $2.3 billion (10). Winter wheat is planted in the fall and harvested in the following summer. Spring and durum wheat are planted in the spring and harvested in the late summer or fall in the same year (8).

Table 1. Major Wheat Producing States in the U.S and the Value of Production in 2006.

State Rank	State	Value of production ($1,000)
1	Kansas	1,339,520
2	North Dakota	1,129,014
3	Montana	703,474
4	Washington	615,593
5	Oklahoma	395,760

Source: (11)

Table 2. Winter, Spring, and Durum Wheat Production in the U.S.

State	Percent of Total Planted Acreage		
	Winter Wheat	Spring wheat	Durum
Kansas	23	--	--
Texas	15	--	--
Oklahoma	14	--	--
Colorado	5	<1	--
South Dakota	4	12	<1
Washington	4	4	--
Montana	4	22	22
Nebraska	4	--	--
Oregon	2	--	--
Ohio	2	--	--
Michigan	2	--	--
Missouri	2	--	--
Arkansas	2	--	--
Idaho	2	4	--
California	1	--	4.5
North Dakota	--	45	68
Minnesota	--	12	<1
Total Planted Acres (in 1,000)	43,350	13,174	2,560

Source: (10)

Weed Management in Wheat Production

Weed management is an essential part of the wheat production to obtain a higher yield. Weeds compete with wheat for water, nutrients, space, and sunlight. They further reduce profits indirectly by hindering harvest operations, harboring diseases and pests, and reducing the crop quality. A healthy wheat crop competes well with weeds when a uniform stand is established (7). The most common grass and broadleaf weed species

found in wheat and the level of infestation of these weeds are given in Tables 3 and 4, respectively.

Table 3. Most Common Grass Weeds in Wheat Production

Weed	% of infested farms	Acres treated (in 1000)	% Treated Acres (of the Total Wheat Acreage)
Wild oats	66.6	10,649	19.0
Green foxtail	42.8	6,914	12.0
Brome (all types)	17.8	4,674	8.0
Yellow foxtail	9.9	1,411	2.0
Annual ryegrass	3.9	685	1.2
Quackgrass	6.3	503	0.9

Source: (8)

Table 4. Most Common Broadleaf Weeds in Wheat Production

Weed	% of infested farms	Acres treated (in 1000)	% Treated Acres (of the Total Wheat Acreage)
Mustards (all types)	42.1	16,760	29
Kochia	41.2	16,105	28
Canada thistle	28..6	8,540	15
Wild buckwheat	27	8,513	15
Russian thistle	12.2	5,157	9
Pigweeds (all types)	16.1	4,482	8
Field bind weed	7.5	3,741	7
Lambsquarters	11.3	3,274	6

Source: (8)

Cultural and Non-Chemical Weed Control Practices

Proper land preparation significantly reduces the weed infestations. Deep tillage breaks up soil compaction and minimizes the risk of herbicide carryover if wheat is planted immediately following another crop. Cleaning of planting and tillage equipment before entering new fields is helpful in avoiding introduction of new weeds (5). Planting wheat seeds contaminated with weed seeds is the most common way introducing weeds into new wheat fields. Use of clean certified seeds for planting minimizes this problem. Proper sanitation practices such as mowing waste areas before the production of weed seeds and crop rotation are also helpful in reducing some weed populations. Wheat competes well with weeds when planted at proper spacing (7). Scouting fields for weeds and taking appropriate control measures also reduce the yield losses and harvesting problems in the wheat production (7).

General Product Information of the New Chemical

Note: The following information on pyroxsulam was direct excerpts from the application submitted by registrant.

Pyroxsulam (XDE-742) is a new systemic post-emergence herbicide developed for the selective control of wild oat, winter annual brome species, annual ryegrass (Italian), and other economically important annual grass and broadleaf weeds in winter and spring wheat including durum. In addition, pyroxsulam suppresses green and yellow foxtail, two problematic grass weeds in spring wheat production. The registrant claims that pyroxsulam controls or suppresses a wide variety of grasses and broadleaf weeds. Pyroxsulam belongs to the family of triazolopyrimidine sulfonamide and it inhibits the enzyme acetolactate synthase (ALS). This enzyme is important for the production of branched-chain amino acids (isoleucine, leucine, and valine) in plants.

GF-1274 and GF-1674 are two herbicide formulations of the technical product pyroxsulam (XDE-742) and the safener cloquintocet-mexyl. Formulation GF-1274 is to be registered for the post-emergence control of annual grasses and broadleaf weeds in winter wheat production. It contains 1:1 ratio of XDE-742 and cloquintocet-methyl. The recommended application rate is 3.5 oz of the product per acre. GF-1274 inhibits growth of susceptible weeds and typical symptoms of weed control may not be noticeable for 1 to 2 weeks after the application, depending upon growing conditions and weed susceptibility. Degree of control and duration of the activity of this product depend on the weed density, weed size, crop competition, growing conditions, and the spray coverage. GF-1274 can be tank mixed with other compatible herbicides to achieve a broader weed control. GF-1274 would be available in WDG (Water Dispersible Granules) formulation containing 0.075 lb of active ingredient per pound of product.

GF-1674 is to be registered for post-emergence control of annual grasses and broadleaf weeds in spring and winter wheat including durum. GF-1674 formulation contains 1:3 ratio of XDE-742: cloquintocet-methyl. The recommended application rate of this herbicide is 6.75 fl oz of product per acre. GF-1674 inhibits the growth of susceptible weeds and typical symptoms of suppressed weeds may not appear for 1-2 weeks after the application, depending upon growing conditions and weed susceptibility. Occasionally, a slight yellowing or height reduction may be observed in the treated crop. If a broader spectrum of weed control is needed GF-1674 may be tank mixed with labeled rates of other compatible herbicides. Best weed control is achieved when grass weeds are treated at 2-leaf to 2-tiller growth stage and broadleaf weeds are before 2 inches tall. GF-1674 would be available in OD (oil dispersion) formulation containing 0.25 lb of active ingredient per pound of product. These products can be applied aerially and using ground spray equipment.

Registrant's Claims for Public Interest

The registrant claims that once registered, pyroxsulam would provide growers a high performance low dose herbicide and a desirable environmental profile with following benefits.

1. Pyroxsulam controls wild oat, brome, annual ryegrass, and a broad spectrum of grass and broadleaf weeds equivalent to leading standards and it provides a crop tolerance equivalent to leading standards.
2. Pyroxsulam provides growers a powerful, new resistance management tool for wild oat and annual ryegrass control.
3. Rapid soil degradation of pyroxsulam allows for flexibility in crop rotations.
4. Pyroxsulam offers a very low application rate and favorable toxicity profile with low mammalian and environmental toxicity.
5. Pyroxsulam is applied as a post-emergence treatment and it offers use patterns that foster integrated pest management (IPM).

ANALYSIS OF REGISTRANT'S CLAIMS

Claim 1. Pyroxsulam controls wild oat, brome, annual ryegrass, and a broad spectrum of grass and broadleaf weeds equivalent to leading standards and it provides a crop tolerance equivalent to leading standards.

To evaluate this claim, BEAD, examined the currently registered herbicides used in wheat production and then analyzed the comparative efficacy data submitted by the registrant.

Many registered herbicides are available as pre-emergence and post-emergence treatments for the control of grass and broadleaf weeds in wheat production (Tables 5, 6, 7, and 8). Wild oat *(Avena fatua)*, Downy brome (*Bromus tectorum* L.), and Italian rye grass (*Lolium multiflorum*), are major troublesome grass weeds in wheat production. Early wild oat control leads to a greater wheat yield due to less direct competition with the crop (5). In general, under heavy wild oat pressure (over 30 plants/square foot) an effective herbicide should be applied to prevent high yield losses (4). Currently available registered herbicides for the control of wild oats are listed in the Table 5.

Downy brome is also a highly troublesome weed in winter wheat production. Heavy infestations of downy brome can reduce wheat yield 30 to 80% (6). It is known by several common names such as cheatgrass, military grass, downy chess, and cheat. Japanese brome (*Bromus japanicus*), ripgut brome (*Bromus rigidus*) are the other brome species found in the wheat production. Registered herbicides available for the control of brome species are given in Table 6.

Table 5. Available Registered Herbicides for Wild Oat Control

Chemical (Trade name)	Mode of Action	Appl. Rate (product)	Time of Application
diclofop-methyl (Hoelon 3EC)	ACCase inhibitor	1.33-2.66 pt/A	Post-emergence. Applied in Fall or Spring
fenoxaprop-ethyl (Puma)	ACCase inhibitor	0.66 pt//A	Post emergence. Applied at wild oat 2-leaf to 2-tiller
mazamethabenz (Assert)	ALS inhibitor	1.5 pt/A	Post-emergence. Applied at 2-leaf to jointing of wheat, wild oat 1-4 leaf stage.
difenzoquat (Avenge)	Shoot inhibitor	0.6-1 lb ai/A	Post-emergence treatment on spring wheat. Apply at 3-5 leaf stage of wild oat.
pinoxaden (Axial)+ cloquintocet-methyl	ACCase inhibitor	8.2 oz/A	Post emergence treatment. Can be tank mixed with other herbicides.

Sources: (3, 4)

Table 6. Registered Herbicides Available for the Control of Brome Species.

Chemical (Trade name)	Mode of Action	Application Rate (product)	Time of Application
metribuzin (Sencor, Lexone)	PS II (inhibits photo system II)	2-8 oz/A	Post-emergence. Wheat with 2 leaves to several tillers in the fall.
sulfosulfuron (Maverick)	ALS inhibitor	2/3 oz/a	Post-emergence. Apply from 3 leaves to jointing of wheat.
imazamox (Beyond)+ UAN (Urea Ammonium Nitrate) liquid fertilizer+ Surfactant	ALS inhibitor	4-6 fl oz/a 1.25% UAN 0.25% Surfactant	Post-emergence. Apply only to wheat varieties possessing the Clearfield trait. Wheat cannot be grazed for 30 days after application.
chlorsulfuron + metsulfuron (Finesse) + metribuzin (Sencor DF)	ALS inhibitor + ALS inhibitor + PS II inhibitor	0.2-0.4 oz/a + 3 oz/a	Post-emergence. Apply this combination when wheat has reached the 4-5 leaf stage of growth.
triasulfuron (Amber) + metribzin) (Sencor DF)	ALS and PS II inhibitors	0.28-0.56 oz/a + 3 oz/a	Post-emergence. Apply this combination when wheat has reached the 3-5 leaf stage of growth.

Sources: (3, 6)

Italian Rye grass (*Lolium multiflorum*) is one of the highly competitive cool season grass weeds in wheat production. Wheat and ryegrass have a same maturity period and it has been reported that that up to 85% yield loss can occur as a result of ryegrass competition. Also, it was estimated that one ryegrass plant per ft^2 can reduce yields by four percent (9). Many registered pre and post emergence herbicides are available for the control of rye grass in the wheat production. These herbicides and their mixtures are listed in Table 7.

Table 7. Available Registered Herbicides for the Control of Annual Ryegrass.

Chemical (Trade name)	Mode of Action	App. Rate (product)	Time of Application
tralkoxydim (Achieve 40DG)	ACCase inhibitor	0.4-0.6 lbs/a	Post-emergence. Apply when Ryegrass is 1-4 leaf stage
chlorsulfuron (Glean)	ALS inhibitor	0.5 oz/a	Pre-emergence. Apply Glean after planting wheat, but prior to emergence of annual ryegrass.
chlorsulfuron+ metsulfuron (Finesse)	ALS inhibitors	0.5 oz/a	Pre-emergence. Apply pre-emergence but prior to ryegrass germination
triasulfuron (Amber)	ALS inhibitors	0.56 oz/a	Pre-emergence. Apply Amber after planting wheat but prior to emergence of annual ryegrass.
diclofop-methyl (Hoelon 3EC)	ACCase inhibitor	1.33 to 2.66 pt/acre	Post-emergence apply in Fall or Spring
chlorsulfuron+ metsulfuron (Finesse) + metribuzin (Sencor DF 3)	ALS inhibitors PS II inhibitor	0.2-0.4 oz/a 3 oz/a	Post-emergence. Apply when wheat has reached the 4 to 5 leaf stage of growth and the cheat has reached the 1-3 leaf stage

Source: (3)

Mustard species (*Brassica* spp.), kochia (*Kochia scoparia*), Canada thistle (*Cirsium arvense*), wild buck wheat (*Polygonum convolvulus*), Russian thistle (*Salsola tragus*), pigweeds (Amarantus spp.), field bind weed (*Convolvulus arvensis*), lambsquarters (Chenopodium album), common chickweed (*Stellaria media*), henbit (*Lamium amplexicaule*), shepherdspurse (*Capsella bursa-pastoris*), and common rag weed (*Ambrosia artemisiifolia*) are the major broadleaf weeds found in wheat production (2, 3). Many effective pre and post emergence herbicides are available for broadleaf weed control in what production. Currently available registered herbicides used for major broadleaf and some grassy weeds are shown in the Table 8.

Table 8. Registered Herbicides Available for Major Broadleaf and Grass Weed Control in Wheat Production.

Active Ingredient (Trade name)	Mode of Action	Rate per Acre (product)	Time of Application	Weeds Controlled
Bromoxynil (Buctril, Moxy, Bronate)	PSII site C inhibitor	1.5 to 2 pts	Emergence to boot stage	Wild buckwheat, common ragweed, lambsquarter, field pennycress, henbit, shepherdspurse, wild mustard.
2,4-D (Weedar, Weedone, Formula 40)	Growth regulator	1 to 2 pts	Tillering to before jointing	Field pennycress, shepherdspurse, wild mustard, ragweeds, lambsquarter, horseweed (marestail), prickly lettuce.
Dicamba (Banvel)	Growth regulator	0.125 to 0.25 pt	Emergence to before jointing	Field pennycress, wild buckwheat, ragweeds, kochia, lambsquarter, horseweed (marestail), prickly lettuce, shepherdspurse.
Thifensulfuron + tribenuron (Harmony Extra)	ALS inhibitor	0.3 to 0.6 oz	After 2-leaf stage but before flag leaf becomes visible	Wild garlic, field pennycress, wild mustard, chickweed, henbit, prickly lettuce, shepherdspurse, wild buckwheat, wild mustard, lambsquarter.
Carfentrazone (Aim)	Protoporphyrinogen oxidase inhibitor	0.33 to 0.66 oz	Before jointing	Catchweed bedstraw, lambsquarter, field pennycress, tansy mustard, flixweed.
chlorsulfuron (Glean)	ALS inhibitor	0.33 oz/acre	Pre-emergence	Controls broadleaf and certain grass weeds.
chlorsulfuron +metsulfuron (Finesse)	ALS inhibitors	0.3-0.4 oz/acre	Pre and post emergence	Recommended for broadleaf and grass weed control in winter and spring wheat including durum.
triasulfuron (Amber)	ALS inhibitor	0.56 oz/acre	Pre-emergence	Recommended for broadleaf weed control in winter and spring wheat except for durum.

Active Ingredient (Trade name)	Mode of Action	Rate per Acre (product)	Time of Application	Weeds Controlled
flucarbazone-sodium (Everest)	ALS inhibitor	0.3-0.4 oz/A	Post-emergence	Apply in spring and durum wheat prior to jointing when the majority of plants are at the 1 to 4 leaf stage. For winter wheat apply in fall or in spring
fluroxypyr + brommoxynil (Starane + Nxtcp)	Growth regulator + PSII site C inhibitor	21.3 fl oz/A	Post emergence	Controls annual broadleaf weeds. Only weeds that have emerged at the time of application will be controlled.
propoxycrbazone (Olympus)	ALS inhibitor	0.9 oz/A	Post-emergence	Controls grasses and broadleaf weeds. Offers contact and residual weed control.
clopyralid (Stinger)	Growth regulator	4-5 fl oz/A	Post-emergence	This herbicide controls some broadleaf weeds not controlled by MCPA or 2,4-D.
MCPA (Chiptox, Rhomene, Rhonox)	Growth regulator	1to 4 pts	Tillering to before jointing	Field pennycress, shepherdspurse, wild mustard, ragweeds, lambsquarter, horsetail, prickly lettuce, wild buckwheat.

Sources: (1, 3)

Comparative Efficacy Data

The registrant submitted a summary of comparative efficacy data from the studies conducted in Australia and Canada, as well as countries in Europe, Asia, and Africa (Table 9). No data were submitted from studies conducted in wheat growing states in the United States. Further, except fenoxaprop-ethyl and bromoxynil, the major herbicides used to control broadleaf and grassy weeds in the U.S. were not included in these studies.

Table 9. Comparative Efficacy Data of Pyroxsulam

Weed	Chemical	Rate (g ai/ha)	Weed Control (%)
Wild oat (*Avena fatua*)	Pyroxsulam + Assist (adjuvant)	15	93.3
	Everest (flucarbazone-sodium) + Frontline + 2,4-D	30+5+560	94.3
	Puma 120 super (fenoxaprop-ethyl) + Buctril M (bromoxynil)	92 +560	86.8
	Horizon (clodinafop) + Refine Extra	56 + 15	93.2
Green foxtail (*Setaria viridis*)	Pyroxsulam + Assist (adjuvant)	15	81.3
	Everest + Frontline + 2,4-D	30+5+560	92.4
	Puma 120 super + Buctril M	92 +560	90.5
Redroot pigweed (*Amaranthus retroflexus*)	Pyroxsulam + Assist (adjuvant)	15	92
	Everest + Frontline + 2,4-D	30+5+560	92
	Puma 120 super + Buctril M	92 +560	85
	Horizon + Refine Extra	56 + 15	78
Hempnettle (*Galeopsis retrahit*)	Pyroxsulam + Assist (adjuvant)	15	91
	Everest + Frontline + 2,4-D	30+5+560	71
	Puma 120 super + Buctril M	92 +560	32
	Horizon (clodinafop) + Refine Extra	56 + 15	84
Chickweed Common (*Stellaria media*)	Pyroxsulam + Assist (adjuvant)	15	94
	Everest + Frontline + 2,4-D	30+5+560	96
	Puma 120 super + Buctril M	92 +560	28
	Horizon + Refine Extra	56 + 15	91
Volunteer Canola (*Brassica napus*)	Pyroxsulam + Assist (adjuvant)	15	92
	Everest + Frontline + 2,4-D	30+5+560	97
	Puma 120 super + Buctril M	92 +560	97
	Horizon + Refine Extra	56 + 15	93
Pennsylvania Smartweed (*Polygonum pensylvanicum*)	Pyroxsulam + Assist (adjuvant)	15	95
	Everest + Frontline + 2,4-D	30+5+560	96
	Puma 120 super + Buctril M	92 +560	82
	Horizon + Refine Extra	56 + 15	93
Wild buckwheat (*Polygonum convolvulus*)	Pyroxsulam + Assist (adjuvant)	15	85
	Everest + Frontline + 2,4-D	30+5+560	95
	Puma 120 super + Buctril M	92 +560	88
	Horizon + Refine Extra	56 + 15	85
Brome sp. (*Bromus* sp.)	Pyroxsulam	18 -18.75	78
	Mesosulfuron + iodosulfuron	15 + 3	68
	Sulfosufuron	20-25	57
	Propoxycarvazone	70	45

Source: (8)

According to the comparative efficacy data submitted by the registrant, leading standard herbicides included in the studies have provided equivalent control of wild oat, brome, annual ryegrass, and a broad spectrum of grass and broadleaf weeds to the new chemical pyroxsulam (Table 9). Based on the submitted information, BEAD believes that there is no need of a new pesticide that is already being met by the currently registered pesticides.

Claim 2. Pyroxsulam provides growers a powerful, new resistance management tool for wild oat and annual ryegrass control.

Pyroxsulam has a mode of action that inhibits Acetolactate Synthase (ALS) enzyme. Many registered herbicides with a similar mode of action that can be applied as post-emergence treatments are currently available for wheat growers (Tables 5, 6, 7, 8). Therefore, based on the submitted information, BEAD believes that the claim of pyroxsulam as a new resistant management tool in wild oat and annual ryegrass control is not substantiated.

Claim 3. Rapid soil degradation of pyroxsulam allows for flexibility in crop rotations.

The registrant claims that pyroxsulam has a rapid soil degradation and favorable toxicity profile with low mammalian and environmental toxicity. BEAD defers these claims to HED and EFED. However, based on submitted information, and on available information concerning wheat production, BEAD believes that the currently available herbicides allow for flexibility in crop rotations.

Claim 4. Pyroxsulam offers a very low application rate and favorable toxicity profile with low mammalian and environmental toxicity.

The registrant claims that pyroxsulam has a rapid soil degradation and favorable toxicity profile with low mammalian and environmental toxicity. BEAD defers these claims to HED and EFED.

Claim 5. Pyroxsulam is applied as a post-emergence treatment and it offers use patterns that foster integrated pest management (IPM).

Based on submitted information, BEAD did not identify any unique attribute of pyroxsulam compared to the currently registered herbicides that would increase adoption of integrated pest management in wheat production.

Economic Considerations

Generally, in a Public Interest Proposal, economic information includes expected market price, expected percent share of the market and an analysis of the primary competitive products. In the application, no such information was included to determine market share or market price to evaluate its impact on the market and economic benefits of pyroxsulam compared to the available registered herbicides.

CONCLUSIONS

Pyroxsulam is a new post-emergence herbicide developed for selective control of wild oat, winter annual brome species, annual ryegrass and other economically important annual grass and broadleaf weeds in winter and spring wheat including durum. The registrant, Dow AgroSciences LLC, claims that new product pyroxsulam (XDE-742) provides a broad spectrum weed control, longer residual activity, and the lower application rates that would result in a reduced environmental load of pesticides in wheat production. Earlier this year, the registrant's application for the reduced risk status for pyroxsulam was denied by the Agency.

The registrant submitted comparative efficacy data from studies conducted in Australia and Canada, as well as countries in Europe, Asia, and Africa, but not in the United States. Currently, many registered herbicides registered for grass and broadleaf weed control in wheat production are available in the market. BEAD reviewed the submission and believes that pyroxsulam provides weed control equivalent to that of the currently available registered herbicides. In addition, data needed to make a direct comparison on efficacy, application rate, and the residual activity of XDE-742 formulations with many registered herbicides used in the U.S. were not included in the submission. Therefore, registrant's claims included in the submission cannot be substantiated.

Based on the information submitted by the registrant, and available information of the currently registered herbicides used in wheat production, BEAD believes that pyrosulfam does not satisfy the two criteria: 1) there is a need for the new pesticide that is not being met by currently registered herbicides and; 2) the benefits from the new pesticide are grater than those from currently registered pesticides or non-chemical control measures that BEAD evaluated for granting the pubic interest status for a pesticide.

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